UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,613	10/26/2001	Jason C. H. Shih	4171-102 CIP	4213

23448 7590 03/22/2005

INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/007,613
Filing Date: October 26, 2001
Appellant(s): H. SHIH, JASON C.

Steven J. Hultquist
For Appellant

EXAMINER'S ANSWER

HL

This is in response to the appeal brief filed on January 3, 2005.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: Applicant's Issue 1 is an objection to the claims, and is therefore not an appealable issue. Thus, the only appealable issue in the case is Issue 2 (the rejection of claims 39-51, 53-56, 63, 71, 73, 74, 80, and 82 under 35 U.S.C. 103(a)).

(7) Grouping of Claims

The rejection of claims 39-51, 53-56, 63, 71, 73, 74, 80, and 82 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

6,448,062	HUTH et al.	9-2002
6,210,639	VLASS et al.	4-2001
H001818	POTGEITER et al.	11-1999
5,171,682	SHIH et al.	12-1992

"WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies: Report of a WHO Consultation," World Health Organization (WHO), March 23-26, 1999 (the WHO reference).

Bolton et al., "Molecular Characteristics of the Major Scrapie Prion Protein," Biochemistry, Vol. 23 No. 25 (December 1984), pages 5898-5906.

Oesch et al., "Properties of the Scrapie Prion Protein: Qualitative Analysis of Protease Resistance, Biochemistry, Vol 33 No 19 (May 1994), pages 5926-5931.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 39-51, 53-56, 63, 71, and 73 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of the WHO reference in view of the teachings of Huth, Vlass, and Potgeiter, and further in view of the teachings of Bolton and Oesch. Claims 74, 80, and 82 stand rejected over the teachings of these references, and additionally in view of Shih. The Applicant has indicated that the claims stand or fall together. Therefore, claim 39 is treated as representative of the rejected claims. This claim describes a system (for the treatment of articles to remove or degrade infectious prion particles) comprising the following elements:

(a) the articles to be treated;

(b) means for heating the articles;

(c) a proteolytic enzyme, wherein the enzyme may be a keratinase; and

(d) means for exposing the articles to the enzyme.

The claim also provides functional language regarding the heating of the articles to be treated to different temperatures at different time points. While the claims recite the functional language regarding the articles of the claimed system, because these limitations describe the heating of the articles to be worked upon, they are describing steps of the method in which the system is to be used. Thus, these limitations are considered only as an intended use of the claimed system, and would not be sufficient to distinguish the claimed system from the prior art so long as the systems taught by the prior art would be capable of performing the method steps.

The WHO reference teaches methods for the sterilization of medical devices from prion infection by treating the device with heat, and then treating the devices with routine

sterilization. Page 14, and page 29 (Annex III). The reference teaches that the device used to heat the articles (in this case- an autoclave) may be used to heat the articles to different temperatures, thereby indicating that it is adjustable. Page 29. Thus, the reference teaches the disinfection of such devices with a system comprising the articles, a heating device, and a sterilizing solution used routinely in the art. The reference does not, however, teach that the sterilization solution comprises a proteolytic enzyme.

Each of Huth, Vlass, and Potgeiter teach compositions useful for the disinfection or cleaning of medical instruments. Huth teaches that numerous types of enzymes may be used in a medical sterilization solution. See e.g., cols 14-15. Similar teachings are provided by Vlass (col. 1, lines 49 and 50, col. 2, lines 22-28, and col. 5), and by Potgeiter (cols. 14-15, and col. 16 at lines 40-47). The additional teachings of these references also provide teachings relating to the limitations of the dependent claims. Each of the references also identifies keratinases as useful enzymes in such compositions. Because each of the Huth, Vlass, and Potgeiter references teaches the use of proteolytic enzymes in solutions for the cleaning of surgical or medical articles, and because the WHO reference teaches the heating and then routine sterilization of the articles, it would have been obvious to those in the art to use keratinase containing compositions in combination with a heating device. Further, because that art indicates that the devices should be treated with the enzymes, it would also have been obvious to include a means for exposing the articles to the enzymes. Thus, in view of the teachings of the WHO document, and the Huth, Vlass, and Potgeiter references, it would have been obvious to those in the art to have a system for cleaning of medical articles of prion proteins comprising the articles, a means of heating the articles, a proteolytic enzyme, and means for exposing the instruments to the enzyme.

The art therefore indicates that the identified system may be used with regards to medical instrument. It is known in the art that such instruments of necessity must be rendered safe from passing infection. In view of this, it would have been equally obvious to those in the art to use such a system for other types of instruments susceptible to infection by prion proteins.

It is noted that, because the combination suggested by the WHO document contains all of the structural elements of the claimed system, the combination would also have the same functionality as the claimed system.

Further, those skilled in the art would have further grounds to have had a reasonable expectation of success that the system would be useful for the purposes indicated by the Applicant due to the additional teachings of Bolton and Oesch. As indicated above, Bolton teaches that purified prion may be deactivated by exposure to an enzyme after being heated to 100° C in a solution. Abstract. Further, the reference indicates that the susceptibility to degradation by the enzyme was due to the denaturation of the protein. See, pages 5900-01. See also, Oesch, page 5928 (also indicating that prions become susceptible to protease degradation after being denatured). Thus, Bolton indicates that heating of enzymes to high temperature (as taught by the WHO document) would result in the denaturation of the prion proteins. Thus, because each of Bolton and Oesch further indicate that denatured prions are susceptible to degradation by proteolytic enzymes, those in the art would have expected the combination suggested by the WHO document, Huth, Vlass, and Potgeiter to be effective in the degradation of prion. This is because they would have expected the heating device suggested by the WHO document to both inactivate and denature the proteins, and that the cleaning agents comprising the enzymes suggested by the other three references would then be effective in further

inactivating and degrading the proteins. The references therefore render the claimed system obvious.

(11) Response to Argument

The Applicant asserts that the prior art rejection described above is deficient in making a prima facie case for obviousness based on the fact that the rejection does not account for the "specific arrangement of the recited elements." While it is not entirely clear what it meant by this argument in traversal, as the claims do not require any particular arrangement of the various structural elements, it appears that the traversal is based upon the indicated functional limitations relating to the heating, and temperatures and times of heating, of the articles to be treated.

As indicated above, the claims provide for a system comprising

(a) the articles to be treated;

(b) means for heating the articles;

(c) a proteolytic enzyme, wherein the enzyme may be a keratinase; and

(d) means for exposing the articles to the enzyme.

As was also indicated above, the claims provide additional functional limitations. The functional limitations are as follows:

> wherein said one or more articles are characterized by a first elevated temperature of at least 40°C and not more than about 150°C during a first duration, wherein said articles are characterized by a second elevated temperature in a range of from about 50°C to about 65°C and exposure to said proteolytic enzyme during a second, subsequent duration.

Under 35 U.S.C. 112, paragraph six, this limitation is a means plus function limitation, the scope of which includes only the structures or materials disclosed in the specification and "equivalents

thereof." See, MPEP 2106 II(C). However, in the present case, the application does not identify any specific means for heating or for exposing the articles to the enzymes. Thus, any device that would be capable of heating the articles to a first and to a second temperature may be used as the heating device. The means for exposing the articles to the enzymes may be any device so usable.

The cited art references teach the use of heating devices for the sterilization of medical instruments. See e.g., Bolton, supra. The teachings of the Bolton reference also demonstrate the use of heating devices that can achieve different temperatures. Page 5901 (indicating the heating of prions to, alternatively, either 65 or 100 °C). See also, the WHO reference on page 29 (teaching the use of an autoclave which, in view of the alternative disclosed embodiments, may be set to different temperatures). Thus, the art teaches the use of means for heating wherein the means for heating may be set to alternative temperature settings as would be required in the claimed device.

With respect to one asserted property of the claimed "arrangement," the Applicant asserts on page 10 of the Appeal Brief that the claims require an arrangement that permit the simultaneous heating and exposure to enzymes of the articles to be treated. However, while the claims require that the articles be heated to certain temperatures (a functional limitation), and that the articles be exposed to the enzymes while they have a particular temperature (also a functional limitation), there is no requirement that the enzymes be introduced to the articles during the heating process. Thus, there is also no inherent requirement that the heating device and the means for exposing the articles to the enzymes have any specific positional relationship. The claims therefore present no requirements on the arrangement of the various parts of the claimed system other than their presence.

The Applicant further argues that the rejection does not teach the functional limitations with reference to the heating of the articles to particular temperature. However, as was indicated above, the claims are not drawn to a method of treating, but to a system comprising certain structural elements: i.e., the claims read on a system (an apparatus) intended to perform a certain function. The identification of the temperatures of the articles is merely an identification of an intended use for the claimed apparatus. In the examination of such an apparatus, section 2114 of the MPEP states that the claimed apparatus "must be distinguished from the prior art in terms of structure rather than function." The MPEP also states that a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" so long as the prior art apparatus teaches all the structural limitations of the claim. MPEP § 2114 (citing, Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)). See also, MPEP § 2115 (quoting the court of In re Casey, 152 USPQ 235 (CCPA 1967), stating "the manner or method in which [a machine for the production of an article] is to be utilized is not germane to the issue of patentability of the machine itself"). In the present case, the Applicant has not argued that the combination of elements disclosed by the prior art would be incapable of performing the claimed method steps of heating the articles. Rather, the Applicant has asserted that the art does not teach the "specific arrangement" of apparatus, or the presence of the articles to be treated in their multiple heated states (i.e. the temperature of the articles to be treated at the first and second time points). Because the claims do not provide structural requirements as to the arrangement of the various devices in the claimed system, and because the Applicant has not demonstrated that the combination of devices

suggested in the prior art would be capable of use in the claimed systems, the Applicant has not structurally distinguished the claimed invention from the prior art.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Zachariah Lucas
Patent Examiner, Art Unit 1648
March 9, 2005

Conferees

James C. Housel
Supervisory Patent Examiner, Art Unit 1648

Long V. Le
Supervisory Patent Examiner, Art Unit 1641

INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709